

REMARKS

Claims 4-6 and 18-22 are pending in the application. Claims 4-6 and 18-22 are rejected. No claims are allowed.

Claims 4 and 5 have been amended to more clearly describe and distinctly claim the subject matter Applicants consider their invention. Specifically, claim 4 has been amended to delete the term “integral” and specify that the contact area is a roughened portion of the inside surface the barrel. Claim 5 has been amended to add the term “further.” Support for the amendment can be found at least at paragraph 0030 of the specification as originally filed.

No new matter has been introduced by these amendments.

Claims 4-6 and 18-23 are presented for further proceedings. Reconsideration of the claim rejections and allowance of the pending claims in view of the amendments above and the following remarks are respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 4-6, 22 and 23 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Greenwood, US 5,120,314 (“Greenwood”). According to the Examiner, it was decided in the Appeal Conference held regarding this application that a § 102 rejection under the Greenwood reference should have been made, as the Examiner had been interpreting “integrally” too narrowly, and since Greenwood discloses that the contact area (50) is attached to the inside surface of the barrel, it is still integral with the barrel.

Applicants respectfully traverse this basis for rejection.

It has long been the law that a claim is anticipated under 35 U.S.C. § 102 only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 631, 638 (Fed. Cir. 1987). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). In addition, for an anticipation rejection to be proper, the reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008) ("But disclosure of each element is not quite enough – this court has long held that '[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim*.'" (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (emphasis in original).

Claim 4 (and thus claims 5, 6, 22 and 23 dependent thereon) has been amended to delete the term "integral" and specify that the contact area is a roughened portion of the inside surface the barrel. As shown in Figure 8 of the subject application, the roughened inside surface of the barrel itself forms the contact area capable of frictionally holding the stopper in a partially deflected position to prevent reflux.

In contrast, even if the annulus (50) in Greenwood is considered “integral” with the syringe barrel (which Applicants dispute), the annulus is not a roughened inside surface of the barrel. Rather, as shown in Figures 1, 3, 6 and 9 of Greenwood, the annulus is lodged on the inside surface of the barrel. As such, Greenwood does not disclose each and every element of the claimed invention arranged as in the claims.

Accordingly, Applicants submit that claims 4-6, 22 and 23 are not anticipated by Greenwood, and reconsideration of this basis for rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

a. Claims 4-6, 22 and 23 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Greenwood. According to the Examiner, even if annulus (50) taught by Greenwood is not considered integral, it would have been obvious to one to have made annulus integral with the inside surface of the barrel in order to make sure that the contact area does not accidentally become dislodged/break away from the inside surface and therefore render the device's protection system useless, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), viz., (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. “[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case

of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As such, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Applicants respectfully traverse this basis for rejection.

As discussed above, claim 4 (and thus claims 5, 6, 22 and 23 dependent thereon) has been amended to delete the term “integral” and specify that the contact area is a roughened portion of the inside surface the barrel. In contrast, annulus (50) in Greenwood is not a roughened inside surface of the barrel. Rather, the annulus in Greenwood is lodged on the inside surface of the barrel. As such, Greenwood fails to teach or suggest every element of the claimed invention.

In addition, Applicants submit that one of skill in the art would not have sought to replace the annulus in Greenwood with a roughed interior barrel surface. The annulus in Greenwood functions to dig into the rubber stopper, thereby locking the piston in the distal position following administration and preventing reuse of the syringe. *See* col. 5, lines 31-49. If the annulus were replaced with a roughened barrel surface, there would be no mechanism for digging into the stopper and locking the piston in the distal position.

Such a modification would destroy the intended function of the syringe in Greenwood, thus teaching away from any such alteration. *See* MPEP § 2143.01 ("If the proposed modification of a reference would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.") (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

Accordingly, Applicants submit that claims 4-6, 22 and 23 are not unpatentable over Greenwood, and reconsideration of this basis for rejection is respectfully requested.

b. Claims 18-20 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Greenwood in view of Lynn, US 5,522,804 ("Lynn"). According to the Examiner, Greenwood discloses the device substantially as claimed except for a tip cap and flush, but states that Lynn discloses a flushing syringe with a tip cap and flushing solution in the chamber of the syringe, wherein the flushing solution is saline. Thus, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood with a cap and the use of saline solution, as taught by Lynn, in order to seal the end of the syringe and to provide the syringe with a flushing solution.

Applicants respectfully traverse this basis for rejection.

Claims 18-20 depend from claim 4. As discussed above with respect to the rejection of claim 4, Greenwood does not disclose or suggest the claimed contact area. Furthermore, the Examiner has pointed to nothing in Lynn that remedies the deficiencies of Greenwood in this respect. As such, the combination of Lynn with Greenwood would

not have rendered the claimed invention obvious. *See In re Rijckaert*, 9 F.3d 1531, 1533 (Fed Cir. 1993).

Accordingly, Applicants submit that claims 18-20 are not unpatentable over Greenwood in view of Lynn, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 4-6 and 18-23 are now in condition for allowance, early notice of which would be appreciated. No fees are believed due at this time. If any fees are due, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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By: /Kenneth M. Zeidner, Reg. #64700/
Kenneth M. Zeidner
Reg. No. 64700
Attorney for Applicants
Tel.: (732) 815-0404

BECTON, DICKINSON AND COMPANY
1 Becton Drive
Franklin Lakes, New Jersey 07417